

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2004/005166

International filing date (day/month/year)  
09.12.2004

Priority date (day/month/year)  
09.12.2003

International Patent Classification (IPC) or both national classification and IPC  
A61M5/145, F16H19/02

Applicant  
ZI MEDICAL PLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

10/582426

International application No.  
PCT/GB2004/005166

IP20Rec'd PCT/PTO 08 JUN 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

|                               |             |      |
|-------------------------------|-------------|------|
| Novelty (N)                   | Yes: Claims | 22   |
|                               | No: Claims  | 1-21 |
| Inventive step (IS)           | Yes: Claims |      |
|                               | No: Claims  | 1-22 |
| Industrial applicability (IA) | Yes: Claims | 1-22 |
|                               | No: Claims  |      |

**2. Citations and explanations**

**see separate sheet**

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)

PCT/GB2004/005166

IP20 Rec'd PCT/PTO 08 JUN 2006

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: FR 1562416  
D2: FR 2541395  
D3: US 4253342  
D4: JP 10297478  
D5: US 5006112

Clarity Article 6 PCT

2. Although **claims 1 and 22** have been drafted as separate independent claims, they appear to relate effectively to the **same subject-matter** and to differ from each other only with regard to the definition of the subject-matter for which protection is sought. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. Hence, these claims do not meet the requirements of Article 6 PCT.

It appears appropriate to file an amended set of claims taking account of the above comments and Article 34(2)(b) PCT. The relevant subject-matter should be defined in a single independent claim followed by dependent claims covering features which are merely optional (Rules 6.3 and 6.4 PCT)

Novelty Article 33(2) PCT

3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1-21** does not appear to be new in the sense of Article 33(2) PCT.

3.1. The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) a medical device (figures 1-12) (for example a drill) comprising:

- claim 1:**
  - a driver means for imparting translational movement to a member comprising an unthreaded shaft (10)
  - at least one bearing (15,15') mounted obliquely to the shaft and having at least one point of contact therewith
  - an actuator (30 or 46 in fig.7) linked to at least one bearing wherein rotation of the shaft causes movement of the bearing along the shaft to affect movement of the actuator
- claims 2-3:** - a single bearing and rotary member (15)
- claims 4-7:** - at least three bearings (Fig. 1-6)
- claims 8-11:** - each bearing (15) is angled with respect to the shaft
- claims 12,21:** - the bearing is spring loaded (19)
- claims 13-14:** - a carriage (46, fig.7)
- claims 16-20:** - a bearing is spring loaded whereby operation of the spring disengages the bearing from the shaft
  - cam and lever (cam 44 and roller 42)
  - reversion (Fig.6a-6b)

3.2. Moreover the document D2 discloses a medical device comprising comprising (figures 1-7):

- claim 1:**
  - a driver means (Fig.1) for imparting translational movement to a member comprising an unthreaded shaft (5)
  - at least one bearing (1,10) mounted obliquely to the shaft and having at least one point of contact therewith (8,11)
  - an actuator (2)
- claims 2-3:** - a single bearing and rotary member (1,10)
- claim 4:** - at least three bearings (Fig.2)
- claim 5:** - each bearing has a bore through which the shaft passes
- claims 6-7:** - the bearing has a pointed inner profile or a flat inner profile
- claims 8-11:** - each bearing is angled with respect to the shaft (Angle  $\beta$ )
- claims 12,21:** - the bearing is spring loaded (17)
- claims 13-14:** - a carriage (2)

3.3. Moreover the document D3 discloses a medical device (figures 1-6) comprising:

- claim 1:**
  - a driver means (Fig.4) with an unthreaded shaft (11)
  - at least one bearing (10,10') mounted obliquely to the shaft
  - an actuator (16)
- claims 2-3:** - a single bearing and rotary member (10)
- claims 4-7:** - at least three bearings (Fig.4)
- claims 8-11:** - each bearing (10) is angled with respect to the shaft
- claims 12,21:** - the bearing is spring loaded (22)
- claims 13-14:** - a carriage (16,16')

3.4. The document D4 also discloses the technical feature of claim 1.

#### **Inventive Step Article 33(3) PCT**

4. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 22 does not appear to involve an inventive step** in the sense of Article 33(3) PCT.

Feature of a syringe driver of **claim 22** is described in document D5 (figure 2) as providing the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in the syringe described in document D1 in order to solve the problem posed.

#### **Further comments**

5. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background art** disclosed in the documents D1-D4 are not mentioned in the description, nor are these documents identified therein.
6. Independent claim 1 is not in the **two-part form** in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part

(Rule 6.3(b)(ii) PCT).